

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

SCHUBERT, Klemens  
Neue Promenade 5  
D-10178 Berlin-Mitte  
ALLEMAGNE

PCT

WRITTEN OPINION  
(PCT Rule 66)

Date of mailing  
(day/month/year)

14.07.2004

Applicant's or agent's file reference  
E01/1322/WO

REPLY DUE

within 1 month(s)  
from the above date of mailing

International application No.  
PCT/EP 03/03288

International filing date (day/month/year)  
28.03.2003

Priority date (day/month/year)  
28.03.2002

International Patent Classification (IPC) or both national classification and IPC  
G06F19/00

Applicant  
EPIGENOMICS AG

1. This written opinion is the **second** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also:** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 28.07.2004

Name and mailing address of the international preliminary examining authority:



European Patent Office - P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk - Pays Bas  
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl  
Fax: +31 70 340 - 3016

Authorized Officer

Türkeli, Y

Formalities officer (incl. extension of time limits)  
Saioudi, N  
Telephone No. +31 70 340-2448



## I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

**Description, Pages**

1-54 as originally filed

**Claims, Numbers**

1-29 as originally filed

**Claims, Pages**

55-60 as originally filed

**Drawings, Sheets**

1-7 as originally filed

**Drawings, Figures**

1-7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:

# WRITTEN OPINION

International application No. PCT/EP 03/03288

- ☐ the claims, Nos.:  
☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

## V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1,22
Inventive step (IS)	Claims	
Industrial applicability (IA)	Claims	

### 2. Citations and explanations

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following document:

- D1: 'Model for Spectral and Chromatographic Data', US 2002/035449 A1 (WILLSE ALAN ET AL) 21 March 2002 (2002-03-21)  
D2: 'Biological Fluid Analysis Using Distance Outlier Detection', WO 97 06418 A (BOEHRINGER MANNHEIM CORP) 20 February 1997 (1997-02-20)

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 22 is not new in the sense of Article 33(2) PCT.

The document **D1** discloses (the references in parentheses applying to this document):

A method of verifying and controlling (page 1, col. 1, par. 2) assays for the analysis of nucleic acid variations ("bio-chip micro-arrays", page 5, col. 1, par. 8) by means of statistical process control (page 2, col. 1, par. 1 and 2), characterized in that variables of each experiment are monitored by measuring deviations of said variables from a reference data set (page 9, col. 2, par. 6) and wherein said experiments or batches thereof are indicated as unsuitable for further interpretation if they exceed predetermined limits (page 10, col. 1, par. 1).

**D1** also discloses:

A computer program product for verifying and controlling (page 1, col. 1, par. 2) assays for the analysis of nucleic acid variations ("bio-chip micro-arrays", page 5, col. 1, par. 8) comprising:

- a) a computer code (page 5, col. 2, par. 5) that receives as input a reference data set (page 9, col. 2, par. 6)
- b) a computer code that receives as input a test data set (page 9, col. 2, par. 6)
- c) a computer code that determines the statistical distance between the reference data set and test data set or elements or subsets thereof (page 10, col. 1, par. 1)
- d) a computer code that identifies individual elements or subsets of the test data set which have a statistical distance larger than that of a predetermined value (page 10, col. 1, par. 1)
- e) a computer readable medium that stores the computer code (page 5, col. 2, par. 5).

Dependent claims 2-21 and 23-29 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, in as much as the technical features disclosed by the documents **D1** and **D2** (see the corresponding passages cited in the international search report).

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 606F19/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 606F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 06418 A (BOEHRINGER MANNHEIM CORP) 20 February 1997 (1997-02-20) abstract; claim 11; figure 4 page 4, paragraph 2 page 7, paragraph 4 -page 8, paragraph 1 page 9, paragraph 2 page 26, paragraph 1	1-29
X	US 2002/035449 A1 (WILLSE ALAN ET AL) 21 March 2002 (2002-03-21) page 1, left-hand column, paragraph 2 page 2, left-hand column, paragraphs 1,2 page 5, left-hand column, paragraph 8 page 9, right-hand column, paragraph 6 -page 10, left-hand column, paragraph 1 -/-	1-10, 22-27

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

3 March 2004

Date of mailing of the international search report

10/03/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax (+31-70) 340-3016

Authorized officer

Türkeli, Y

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>TEPPOLA P ET AL: "Principal component analysis, contribution plots and feature weights in the monitoring of sequential process data from a paper machine's wet end"</p> <p>CHEMOMETRICS AND INTELLIGENT LABORATORY SYSTEMS, ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL, vol. 44, no. 1-2, 14 December 1998 (1998-12-14), pages 307-317, XP004152703 ISSN: 0169-7439 abstract; figure 4 section 2.4 section 5.3</p>	1-29
A	<p>WO 00 79465 A (EOS BIOTECHNOLOGY INC ; GLYNNE RICHARD (US); GHANDOUR GHASSAN (US)) 28 December 2000 (2000-12-28) page 3, paragraph 2 page 6, paragraph 3 page 20, paragraph 1 page 21, paragraph 4 -page 22, paragraph 2</p>	1-29

## INTERNATIONAL SEARCH REPORT

Application No

PCT/EP 03/03288

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9706418	A	20-02-1997	US 5606164 A	25-02-1997
			AU 711324 B2	14-10-1999
			AU 6644896 A	05-03-1997
			CA 2228844 A1	20-02-1997
			EP 0846253 A1	10-06-1998
			JP 11510604 T	14-09-1999
			JP 3323512 B2	09-09-2002
			WO 9706418 A1	20-02-1997
US 2002035449	A1	21-03-2002	US 6253162 B1	26-06-2001
			US 2001027382 A1	04-10-2001
			CA 2447888 A1	05-12-2002
			WO 02096540 A1	05-12-2002
			AU 4202700 A	23-10-2000
			CA 2368762 A1	12-10-2000
			EP 1175649 A2	30-01-2002
			JP 2002541556 T	03-12-2002
			WO 0060493 A2	12-10-2000
WO 0079465	A	28-12-2000	US 6516276 B1	04-02-2003
			AU 5495900 A	09-01-2001
			WO 0079465 A2	28-12-2000